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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,104	09/25/2006	Wouter De Graaff	2004.834US	7020

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PATENT DEPARTMENT
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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	**PAPER NUMBER**
4173	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,104	DE GRAAFF ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☒ Claim(s) *7-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending and currently under consideration.

Claim Objections

Claims 7-8 is objected to because of the following informalities: There is a typographical error between "80" and "g/day". A character appears to be missing. Claim 8 is missing a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating sexually transmitted diseases, does not reasonably provide enablement for prevention of sexually transmitted diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prevent sexually transmitted diseases commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The invention relates to a contraception preparation. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites http://www.webmd.com/sex-relationships/understanding-stds-basics (accessed 1/22/2008). The reference discloses that sexually transmitted diseases (STDs) are among the most common contagious diseases (see entire document). More than 65 million Americans have an incurable STD. A person can acquire an STD by vaginal, anal, or oral sex, but also through skin to skin contact. A person can be infected with trichomoniasis by contact with damp or moist objects such as towels, wet clothing or toilet seats. The germs that cause STDs hide in semen, blood, vaginal secretions, and sometimes saliva. Most of the organisms are spread by sexual intercourse, but some, such as those that cause genital herpes and genital warts, may be spread through skin contact. For example, a person can contract hepatitis B by sharing personal items, such as toothbrushes or razors, with someone who has it.

2. The breadth of the claims

Since the instant specification provides no limiting definition of the term "prevent", the examiner will adopt the broadest reasonable interpretation for same. Webster's Ninth New Collegiate Dictionary defines "prevention" as "to keep from happening or existing", i.e., to completely eradicate.

The claims are thus very broad insofar as they recite the "prevention" of sexually transmitted diseases,, i.e., the complete eradication of same. While such "prevention"

might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live; contraction is always a risk.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for prevention of STDs. No reasonably specific guidance is provided concerning useful therapeutic protocols for preventing STDs, other than treating STDs. The latter is corroborated by the working examples.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent STDs as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention. The phrase "wherein the drug delivery system does not need special storage and transportation conditions at a temperature below room temperature" is vague and indefinite. It is unclear what "does not need special storage and transportation conditions" means, what parameters are involved, what material characteristics or effects are preserved or not preserved by special storage, etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0876815 ('815).

Instant Claims 1-2, 6, 8, and 10 are directed to a drug delivery system. '815 discloses a drug delivery system comprising at least one compartment comprising (i) a thermoplastic polymer core containing a mixture of progestogenic and estrogenic compounds and (ii) a thermoplastic polymer skin, wherein the thermoplastic polymer skin is permeable to the progestogenic and estrogenic compounds (see abstract; p 2, ln 50 to p 3, ln 12; Examples 1-5). Polyethylene vinylacetate copolymer (Evatane®) is an

exemplified material for both the thermoplastic polymer core and thermoplastic polymer skin (see p 3, ln 5-8; p 3, ln 26-30; p 4, ln 19-20; Examples 1-5). Etonogestrel (a steroid) is exemplified as a progestogenic compound (see Examples 1-5). Ethinyl estradiol (a steroid) is exemplified as an estrogenic compound (see Examples 1-5). The progestogenic compound is dissolved in the core polymer in a relatively low degree of supersaturation, preferably being about 1 to about 6 times of the amount of weight necessary for obtaining the saturation concentration of said progestogenic steroid in said core polymer at 25 °C (see p 2, ln 54 to p 3, ln 4; Claim 4). The Examiner is interpreting a core wherein the progestogenic compound is dissolved at about 1 times the amount of weight necessary for obtaining the saturation concentration at 25 °C, as disclosed by '815, to reasonably encompass values "up to a concentration below the saturation level at 25 °C", as required by the Instant Claims (see '815, Example 1). In addition, '815 discloses that an essential element of the patent invention is to have the progestogenic steroid dissolved in the core material in a relatively low degree of supersaturation and the importance of keeping the steroid dissolved in a low concentration to improve the shelf life of the product (see p 4, ln 6-24; Reference Example).

Instant Claims 3-5 are directed to a drug delivery system with required weight percent and thickness ranges of the polyethylene vinylacetate components. The polyethylene vinylacetate copolymer of the core disclosed by '815 is a copolymer containing 25 to 35% vinylacetate content (see p 4, ln 3-4). The polyethylene vinyl

copolymer of the skin is a copolymer having a thickness of 40 to 300 microns and contains 5 to 15% vinylacetate content (see p 3, ln 54-58).

Instant Claim 7 is directed to a drug delivery system wherein the release on day 21 of etonogestrel of the drug delivery system is 80 (missing character) grams/day or more. The Examiner is interpreting the missing character to possibly be lower case Mu, and therefore the release of etonogestrel is 80 micrograms/day or more. While '815 does not disclose this property, appreciation of this property is not, in itself, patentable subject matter. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). MPEP 2112, I.

Instant Claim 9 is directed to a drug delivery system wherein the system is ring shaped. The drug delivery system disclosed by '815 is ring shaped (see p 3, ln 42).

Instant Claim 11 is directed to a drug delivery system wherein the system is for intravaginal use. "For intravaginal use" is an intended use and is not given patentable weight. It is noted, however, that intravaginal application of the disclosed drug delivery system is taught by '815 (see p 2, ln 3-5).

Instant Claim 12 is directed to a drug delivery system that does not need special storage and transportation conditions at a temperature below room temperature. As

indicated above, it is unclear what parameters are involved with the product not needing special storage and transportation conditions. The only required structural element of Instant Claim 12 is the drug delivery system according to Instant Claim 1. This drug delivery system is disclosed by '815.

Instant Claims 13-14 are directed to a method of manufacturing a drug delivery system. '815 discloses a method of manufacturing a drug delivery system comprising the steps of (i) producing a medicated polyethylene vinylacetate copolymer core granulate, comprising a progestogenic and an estrogenic compound, (ii) co-extruding the core granulate with a polyethylene vinylacetate copolymer skin granulate, resulting in a copolymer fiber comprising a core covered by a skin, and (iii) assembling the fiber into a ring (see p 4, ln 25-28; Examples 1-5). '815 further discloses incorporation of magnesium stearate (a lubricant) into the core granulate (see Examples 1-5). '815 does not explicitly state that the mixture of core granulate is a homogenous mixture, but the homogeneity of this mixture is inherent in the disclosed invention. This inherency is supported by the need to keep the progestogenic and estrogenic compounds dissolved in the polyethylene vinylacetate copolymer (see p 3, ln 26-27).

Instant Claim 15 is directed to a contraceptive kit or kit for hormone-replacement therapy. The kit only requires the presence of the drug delivery system according to Instant Claim 1. All the recited elements of the kit (i.e. the drug delivery system according to Instant Claim 1) are disclosed by '815. Furthermore, '815 discloses the role of these elements in contraception and hormone-replacement therapy (see p 3, ln 42-43).

Instant Claim 16 is directed to a combination preparation. The combination preparation only requires the presence of the drug delivery system according to Instant Claim 1. All the recited elements of the kit (i.e. the drug delivery system according to Instant Claim 1) are disclosed by '815. '815 discloses the role of these elements in contraception (see p 3, ln 42-43). '815 does not disclose the role of these elements in treating sexually transmitted diseases, however, appreciation of this property is not, in itself, patentable subject matter. See MPEP 2112, I.

The Examiner is interpreting "combination" in Instant Claim 16 to reasonably refer to the combination of compartments of the drug delivery system and/or a combination of uses of the drug delivery system.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Dickinson
Examiner
AU 1618

January 23, 2008

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SUPERVISORY PATENT EXAMINER